

PTO SB 08B (04-03)

Approved for use through 04/30/2003, OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1470 (1-94)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Page

1

of

1

Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Nichols, Christopher J.
Attorney Docket Number	020167-000120US

CONSIDERED; DO NOT PRINT.

U.S. PATENT DOCUMENTS

Examiner	Cite No.	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CGN	AA	US-5,422,110	06/06/1995	Potter et al.	
CGN	AB	US5110054A	n/a	Gan	

FOREIGN PATENT DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
CGN	AC	EP	0 645 454	A2	03/29/1995	Lunin et al.		
CGN	AD	WO	96/23868	A1	08/08/1996	G.D. Searle & Co		
CGN	AE	CA	1,341,211		03/27/2001	Hoechst Aktiengesellschaft		

NON PATENT LITERATURE DOCUMENTS

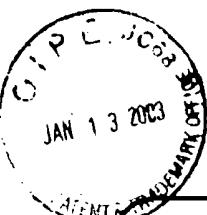
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issuue number(s), publisher, city and/or country where published.	T ²
CGN	AF	ENZOIS DATABASE, Accession number 100407207028. Samuelsson et al., 1994, "Enhanced <i>in vitro</i> refolding of insulin-like growth factor I using a solubilizing fusion partner," <i>Biochemistry</i> 33(14):4207-4211 (abstract)	
CGN	AG	ENZOIS DATABASE, Accession number, PREG100700706120. Klappa et al., 1997, "Interactions between protein disulphide isomerase and peptides," <i>European Journal of Biochemistry</i> 248(1):37-42 (abstract)	

Examiner Signature	<i>Gillie B</i>	Date Considered	9/11/2003
--------------------	-----------------	-----------------	-----------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

²Applicant's unique citation designation number (optional). ³Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.
59059940 v1



PTO SB 08B (10-01)

Approved for use through 10/31/2002 OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2 of 3

Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Seoud, Christine J. NM-1075
Attorney Docket Number	020167-000120US

RECEIVED

JAN 16 2003

TECH CENTER 1600/2900

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CGD	AG	U. Shinde and M. Inouye, "Intramolecular chaperones and protein folding," <i>TIBS</i> , (1993), Vol. 18, pp. 442-446.	—
CGD	AH	M. Inouye, "Intramolecular Chaperone: The Role of the Pro-Peptide in Protein Folding," <i>Enzyme</i> , (1991), Vol. 45, pp. 314-321.	—
CGD	AI	M. Ikehara, et al., "Synthesis of a gene for human growth hormone and its expression in <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , (Oct. 1984), Vol. 81, pp. 5956-5960.	—
CGD	AJ	Watson et al., <i>Recombinant DNA—A Short Course</i> , Scientific American Books, W.H. Freeman Co., NY, (1983), pp. 231-241.	—
CGD	AK	Norman and Litwack, "Pancreatic Hormones: Insulin and Glucagon," in <i>Hormones</i> , Academic Press, Inc., NY, (1987), pp 264-317.	—
CGD	AL	I. Johnson, "Human Insulin from Recombinant DNA Technology," <i>Science</i> , (Feb. 11, 1983), Vol. 219, pp. 632-637.	—
CGD	AM	D. Williams, et al., "Cytoplasmic Inclusion Bodies in <i>Escherichia coli</i> Producing Biosynthetic Human Insulin Proteins," <i>Science</i> , (Feb. 5, 1982), Vol. 215, pp. 687-689.	—
CGD	AN	R. Burgess, "Protein Purification," in <i>Protein Engineering</i> , Oxender, D.L., Fox, C.F., Eds.; Alan R. Liss, Inc. NY, (1987), pp. 71-82.	—
CGD	AO	R.E. Chance, et al., "The Production of Human Insulin Using Recombinant DNA Technology and a New Chain Combination Procedure," in <i>Peptides: Synthesis-Structure-Function</i> , Pierce Chem. Co., Rockford, IL, (1981), pp. 721-728.	—
CGD	AP	B.H. Frank and R.E. Chance, "The Preparation and characterization of human insulin of recombinant DNA origin," in <i>Therapeutic Agents Produced by Genetic Engineering "Quo Vadis?" Symposium</i> , (May 29-30, 1985), Sanofi Group, Toulouse-Labège, France, pp. 137-148.	—
CGD	AQ	R.E. Chance, et al., "Chemical, Physical, and Biological Properties of Recombinant Human Insulin," in J. L. Gueriguian <i>Insulins, Growth Hormone, and Recombinant DNA Technology</i> , Raven Press, NY, (1981), pp. 71-85.	—
CGD	AR	R. D. Johnson, "The Processing of Biomacromolecules: A Challenge for the Eighties," <i>Fluid Phase Equilib.</i> , (1986), 29:109-123.	—
CGD	AS	D. V. Goeddel, et al., "Expression in <i>Escherichia coli</i> of chemically synthesized genes for human insulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Jan 1979), No. 1, pp. 106-110.	—

Examiner Signature

Date Considered

2/3/2003

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

WC 9049707 v1



PTO SB 08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

3

of

3

Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Seaud, Christine J.

Attorney Docket Number

020167-000120US

RECEIVED

JAN 6 2003

TECH CENTER 1600/2900

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CB	AT	J. P. Burnett, "Commercial Production of Recombinant DNA-Derived Products," in <i>Experimental Manipulation of Gene Expression</i> , Academic Press, NY, (1983), pp. 259-277.	—
CB	AU	J. Etienne-Decent, "Regulation of Protein Synthesis," in <i>Genetic Biochemistry: From Gene to Protein</i> , Ellis Horwood Limited, Chichester, U.K., (1988), pp. 125-127.	—
CB	AV	S. M. Wheelwright, <i>Protein Purification: Design and Scale up of Downstream Processing</i> , Oxford University Press, NY, (1991), p.217.	—
CB	AW	B.H. Frank and R.E. Chance, "Two Routes for Producing Human Insulin Utilizing Recombinant DNA Technology," <i>Munch. Med. Wschr.</i> , (1983), Vol. 125, Suppl. 1, pp. S14-S20.	—
CB	AX	E. P. Kroeff, et al, "Production Scale Purification of Biosynthetic Human Insulin by Reversed-Phase High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , (1989), Vol. 461, pp. 45-61.	—
CB	AY	H. V. Tottrup and S. Carlsen, "A Process for the Production of Human Proinsulin in <i>Saccharomyces cerevisiae</i> ," <i>Biotechnol. Bioeng.</i> , (1990), Vol. 35, pp. 339-348.	—
CB	AZ	L. R. Castellanos-Serra, et al., "Expression and folding of an interleukin-2-proinsulin fusion protein and its conversion into insulin by a single step enzymatic removal of the C-peptide and the N-terminal fused sequence," <i>FEBS Letters</i> , (1996), Vol. 378, pp. 171-176.	—
CB	BA	L. Villa-Komaroff, et al., "A bacterial clone synthesizing proinsulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Aug. 1978), Vol. 75, No. 8, pp. 3727-3731.	—
CB	BB	L. Thim, et al., "Secretion and processing of insulin precursors in yeast," <i>Proc. Natl. Acad. Sci. USA</i> , (Sept. 1986), Vol. 83, pp. 6766-6770.	—
CB	BC	I. V. Diers et al., "Yeast Fermentation Processes for Insulin Production," in Y. H. Chiu <i>Drug Biotechnology Regulations: Scientific Basis and Practices</i> , Marcel Dekker, Inc., NY, (1991), pp. 166-176.	—
CB	BD	M. R. Ladisch and K. L. Kohlmann, "Recombinant Human Insulin," <i>Biotechnol. Prog.</i> , (1992), Vol. 8, pp. 469-478.	—

Examiner
Signature

Date
Considered

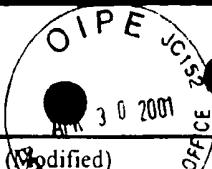
3/6/2003

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

WC 9049707 v1



FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Attorney Docket No.: 20167-000120US		Application No.: 09/423,100		
		Applicant: Dr. Zhong-Ru Gan				
		Filing Date: October 29, 1999		Group: 1798 1647		
Reference Designation		U.S. PATENT DOCUMENTS				Page 1
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
GDAA	6,001,604	12/14/99	Hartman et al.			
GDAB	4,916,212	04/10/90	Markussen et al.			
GDAC	4,342,832	08/03/82	Goeddel et al.			
GDAE	5,254,463	10/19/93	de Boer et al.			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
GA AE	WO 96/20724	07/11/96	PCT			
GA AF	WO 97/18233	05/22/97	PCT			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
EXAMINER	DATE CONSIDERED <u>3/6/2003</u>					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

MAY 1 2001

TC 1700